

1 Amendments to the Claims:

2 This listing of claims will replace all prior versions, and listings of claims in the
3 application:

4 Listing of Claims:

5

6 1. (currently amended) A pharmaceutical composition comprising:
7 a drug retained in a solid matrix in a manner causing release of said drug
8 from said solid matrix when said solid matrix is in the stomach,
9 said solid matrix when in the stomach being of a size large enough
10 to promote retention of said solid matrix in the stomach during the
11 fed mode, and

12 a fed mode inducing agent selected from the group consisting of:

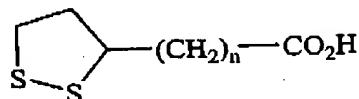
13 (a) glycine, glycylglycine and salts thereof,

14 (b) C₄-C₈-sugar alcohols;

15 (e b) alkali and alkaline earth metal docusates,

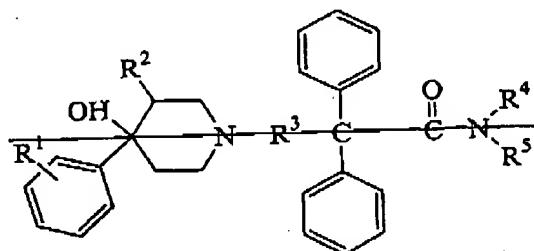
16 (e c) β-casomorphins,

17 (e d) dithioorganic acids of the formula



18 in which n is 3 to 13,

19 (f) 2,2-diaryl-4-(4' aryl-4'-hydroxypiperidine)butyramides of the
20 formula
21



22 in which:

23 R¹ is a member selected from the group consisting of H,
24 lower alkyl, and halo;

25

26

R^2 is a member selected from the group consisting of H and methyl;

27

R^3 is a member selected from the group consisting of CH_2CH_2 and $CH(CH_3)CH_2$;

28

R^4 is lower alkyl, and

29

R^5 is lower alkyl;

30

([g] e) arginine and arginine salts,

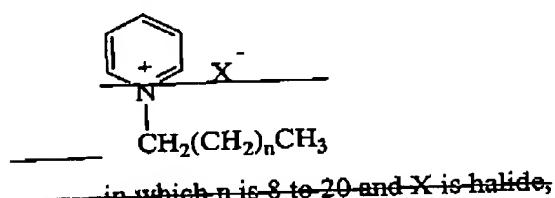
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(h) the dipeptide Trp-Trp and salts thereof,

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(i) alkyl pyridinium halides of the formula

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in which n is 8 to 20 and X is halide;

35

(j) dihydroxybenzoic acids;

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(k) stevioside;

(l) alkyl esters of N-L- α -aspartyl-L-phenylalanine;

37

(m) aspartic acid and salts thereof; and

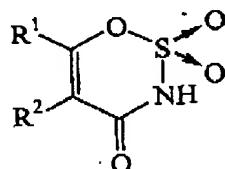
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(n) 3,4-dihydro-1,2,3-oxathiazin-4-ones of the formula

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in which R¹ and R² are independently selected from the group consisting of H and C₁-C₁₀ alkyl, and salts thereof;

43

44

in an amount that causes onset of the fed mode.

45

1 2. (original) A pharmaceutical composition in accordance with claim 1
2 in which said fed mode inducing agent is retained in said solid matrix with said drug, said
3 solid matrix causing release of both said fed mode reducing agent and said drug in a
4 sustained manner.

5 3.(original) A pharmaceutical composition in accordance with claim 1
6 in which said fed mode inducing agent resides in a surface coating or layer on said solid
7 matrix, said surface coating or layer permitting substantially immediate release of said fed
8 mode reducing agent upon contact with gastric fluid while said solid matrix causes
9 release of said drug in a sustained manner.

10 4. (original) A pharmaceutical composition in accordance with claim 1
11 in which said fed mode inducing agent is separate from said solid matrix, said solid
12 matrix causing release of drug in a sustained manner.

13 5.(original) A pharmaceutical composition in accordance with claim 1
14 in which the size of said solid matrix prior to ingestion is sufficiently large to promote
15 retention of said solid matrix in the stomach during the fed mode.

16 6.(original) A pharmaceutical composition in accordance with claim 1
17 in which said solid matrix swells or expands upon contact with gastric fluid to a size
18 sufficiently large to promote retention of said solid matrix in the stomach during the fed
19 mode.

20 7.(currently amended) A pharmaceutical composition in accordance with
21 claim 1 in which said fed mode inducing agent is a member selected from the group
22 consisting of glycine, glycylglycine, and salts thereof.

1 8.(original) A pharmaceutical composition in accordance with claim 7
2 in which the amount of said fed mode inducing agent is from about 1 mg to about
3 500 mg.

4 9.(original) A pharmaceutical composition in accordance with claim 7
5 in which the amount of said fed mode inducing agent is from about 5 mg to about
6 150 mg.

7 10 - 13. (cancelled)

8 14. (original) A pharmaceutical composition in accordance with claim 1
9 in which said fed mode inducing agent is a member selected from the group consisting of
10 alkali and alkaline earth metal docusates.

11 15.(original) A pharmaceutical composition in accordance with claim 14
12 in which said fed mode inducing agent is a member selected from the group consisting of
13 calcium docusate and sodium docusate.

14 16.(original) A pharmaceutical composition in accordance with claim 14
15 in which said fed mode inducing agent is sodium docusate.

16 17. (original) A pharmaceutical composition in accordance with claim 14
17 in which the amount of said fed mode inducing agent is from about 30 mg to about
18 1000 mg.

19 18.(original) A pharmaceutical composition in accordance with claim 14
20 in which the amount of said fed mode inducing agent is from about 50 mg to about
21 400 mg.

22 19.(original) A pharmaceutical composition in accordance with claim 1
23 in which said fed mode inducing agent is a β -casomorphin.

1 20.(original) A pharmaceutical composition in accordance with claim 19
2 in which said β -casomorphin is bovine β -casomorphin.

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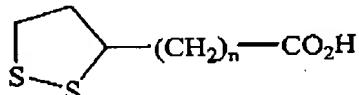
4 21.(original) A pharmaceutical composition in accordance with claim 19
5 in which the amount of said β -casomorphin is from about 1 mg to about 300 mg.

6

7 22.(original) A pharmaceutical composition in accordance with claim 19
8 in which the amount of said β -casomorphin is from about 5 mg to about 150 mg.

9

10 23.(original) A pharmaceutical composition in accordance with claim 19
11 in which said fed mode inducing agent is a dithioorganic acid of the formula



15 24.(original) A pharmaceutical composition in accordance with claim 23
16 in which said dithioorganic acid is α -lipoic acid.

17

18 25.(original) A pharmaceutical composition in accordance with claim 23
19 in which the amount of said dithioorganic acid is from about 30 mg to about 1000 mg.

20

21 26.(original) A pharmaceutical composition in accordance with claim 23
22 in which the amount of said dithioorganic acid is from about 40 mg to about 300 mg.

23

24 27-31 (canceled)

25

26 32.(original) A pharmaceutical composition in accordance with claim 1
27 in which said fed mode inducing agent is a member selected from the group consisting of
28 arginine and arginine salts.

29

30 33.(original) A pharmaceutical composition in accordance with claim 32
31 in which the amount of said fed mode inducing agent is from about 3 mg to about 300
32 mg.

33

34 34.(original) A pharmaceutical composition in accordance with claim 32
35 in which the amount of said fed mode inducing agent is from about 30 mg to about 150
36 mg.

37

38 35-46 (canceled)

39 47.(original) A pharmaceutical composition in accordance with claim 1
40 in which said fed mode inducing agent is retained in said dosage form in such a manner
41 that said fed mode inducing agent is released substantially immediately into gastric fluid
42 upon contact of said dosage form with said gastric fluid while said drug is released into
43 said gastric fluid in a sustained manner by dissolution and diffusion of said drug out of
44 said solid matrix, by erosion or dissolution of said matrix, or by osmotic pressure within
45 said solid matrix.

46

47 48.(original) A pharmaceutical composition in accordance with claim 1
48 in which said fed mode inducing agent is retained in said dosage form in such a manner
49 that both said drug and said fed mode inducing agent are released into gastric fluid in a
50 sustained manner by dissolution and diffusion of said drug and said fed mode inducing
51 agent out of said solid matrix, by erosion or dissolution of said matrix, or by osmotic
52 pressure within said solid matrix.

53

1 49.(original) A pharmaceutical composition in accordance with claim 1
2 in which said solid matrix is a member selected from the group consisting of cellulose
3 polymers and polyethylene oxide.

4 50.(original) A pharmaceutical composition in accordance with claim 49
5 in which said solid matrix is a member selected from the group consisting of
6 hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose,
7 hydroxypropylmethylcellulose, carboxymethylcellulose, and polyethylene oxide.
8

9 51.(original) A pharmaceutical composition in accordance with claim 50
10 in which said solid matrix is a member selected from the group consisting of
11 hydroxyethylcellulose, hydroxypropylcellulose, and polyethylene oxide.
12

13 52.(original) A pharmaceutical composition in accordance with claim 1
14 in which said fed mode inducing agent is contained in a solid coating adhering to a
15 surface of said solid matrix.
16

17 53.(original) A pharmaceutical composition in accordance with claim 52
18 in which said solid coating is comprised of said fed mode inducing agent suspended in a
19 water-soluble matrix.
20

21 54.(original) A pharmaceutical composition in accordance with claim 52
22 in which said water-soluble matrix is a member selected from the group consisting of
23 cellulosics, vinyls, glycols and carbohydrates.
24

25 55.(original) A pharmaceutical composition in accordance with claim 52
26 in which said water-soluble matrix is a member selected from the group consisting of
27 sodium carboxymethylcellulose, sodium starch glycolate, crospovidone, microcrystalline
28 cellulose, lactose, and substituted hydroxypropylcellulose.

1 56-96 (canceled)

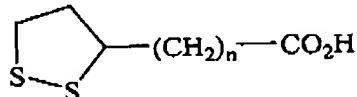
2 97.(original) A pharmaceutical composition comprising:
3 a drug retained in a first solid matrix in a manner causing release of said
4 drug from first said solid matrix when said first solid matrix is in
5 the stomach, said solid first matrix when in the stomach being of a
6 size large enough to promote the retention of said first solid matrix
7 in the stomach during the fed mode, and
8 a pharmacological fed mode inducing agent active in inducing onset of the
9 fed mode, said fed mode inducing agent retained in a second solid
10 matrix configured to release said fed mode inducing agent into the
11 stomach in a sustained manner.

12

13 98.(original) A pharmaceutical composition in accordance with claim 97
14 in which said first solid matrix and said second solid matrix are a common single matrix.

15 99.(original) A pharmaceutical composition in accordance with claim
16 98 in which said fed mode inducing agent is sufficiently potent that onset of said fed mode
17 results from release of an amount of said fed mode inducing agent that is less than
18 500 mg.

19 100. (new) A pharmaceutical composition in accordance with claim 1 in
20 which the fed mode inducing agent is selected from the group consisting of dithioorganic
21 acids of the formula



in which n is 3 to 13.

1 101. (new) A pharmaceutical composition in accordance with claim 100 in
2 which the fed mode inducing agent is acesulfame.

3 102. (new) A pharmaceutical composition in accordance with claim 100
4 in which the amount of said dithioorganic acid is from about 30 to about 1000 mg.

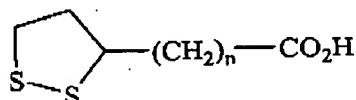
5 103. (new) A pharmaceutical composition in accordance with claim 100
6 in which the amount of said dithioorganic acid is from about 30 to about 1000 mg.

7 104. (new) A pharmaceutical composition in accordance with claim 100 in
8 which the amount of said dithioorganic acid is from about 40 to about 300 mg.

9
10 105. (new) A sustained release pharmaceutical composition comprising:
11 a drug retained in a solid matrix in a manner causing release of said drug
12 from said solid matrix when said solid matrix is in the stomach, said solid matrix
13 when in the stomach being of a size large enough to promote retention of said
14 solid matrix in the stomach during the fed mode, and

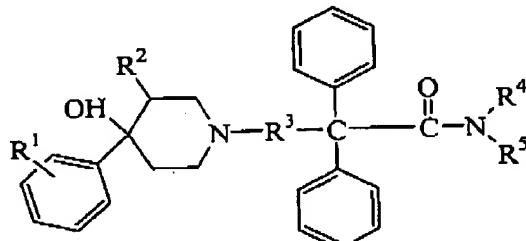
15 a fed mode inducing agent selected from the group consisting of:

- 16 (a) glycylglycine and salts thereof,
17 (b) C₄-C₈ sugar alcohols,
18 (c) alkali and alkaline earth metal docusates,
19 (d) β-casomorphins,
20 (e) dithioorganic acids of the formula



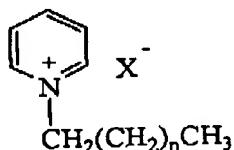
21 in which n is 3 to 13,

22 (f) 2,2-diaryl-4-(4'-aryl-4'-hydroxypiperidino)butyramides of the
23 formula



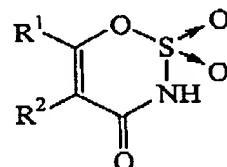
25 in which:

27 R¹ is a member selected from the group consisting of H,
 28 lower alkyl, and halo,
 29 R² is a member selected from the group consisting of H and
 30 methyl,
 31 R³ is a member selected from the group consisting of —
 32 CH₂CH₂— and —CH(CH₃)CH₂—,
 33 R⁴ is lower alkyl, and
 34 R⁵ is lower alkyl,
 35 (g) arginine and arginine salts,
 36 (h) the dipeptide Trp-Trp and salts thereof,
 37 (i) alkyl pyridinium halides of the formula



38 in which n is 8 to 20 and X is halide,

- 39
 40 (j) dihydroxybenzoic acids,
 41 (k) stevioside,
 42 (l) alkyl esters of N-L- α -aspartyl L-phenylalanine,
 43 (m) aspartic acid and salts thereof, and
 44 (n) 3,4-dihydro-1,2,3-oxathiazin-4-ones of the formula



45 in which R¹ and R² are independently selected from the
 46 group consisting of H and C₁-C₁₀ alkyl, and salts thereof
 47 in an amount that causes onset of the fed mode.

49

50 106.(new) A pharmaceutical composition in accordance with claim 105 in
 51 which said fed mode inducing agent is retained in said solid matrix with said drug, said
 52 solid matrix causing release of both said fed mode reducing agent and said drug in a
 53 sustained manner.

1 107.(new) A pharmaceutical composition in accordance with claim 105 in
2 which said fed mode inducing agent resides in a surface coating or layer on said solid
3 matrix, said surface coating or layer permitting substantially immediate release of said fed
4 mode reducing agent upon contact with gastric fluid while said solid matrix causes
5 release of said drug in a sustained manner.

6 108.(new) A pharmaceutical composition in accordance with claim
7 105 in which said fed mode inducing agent is separate from said solid matrix, said solid
8 matrix causing release of drug in a sustained manner.
9

10 109.(new) A pharmaceutical composition in accordance with claim
11 105 in which the size of said solid matrix prior to ingestion is sufficiently large to
12 promote retention of said solid matrix in the stomach during the fed mode.
13

14 110.(new) A pharmaceutical composition in accordance with claim
15 105 in which said solid matrix swells or expands upon contact with gastric fluid to a size
16 sufficiently large to promote retention of said solid matrix in the stomach during the fed
17 mode.

18 111.(new) A pharmaceutical composition in accordance with claim
19 105 in which said fed mode inducing agent is a member selected from the group
20 consisting of glycylglycine and salts thereof.

21 112. (new) A pharmaceutical composition in accordance with claim
22 105 in which said fed mode inducing agent is a C₄-C₈ sugar alcohol.

23 113.(new) A pharmaceutical composition in accordance with claim
24 105 in which said C₄-C₈ sugar alcohol is xylitol.

25 114.(new) A pharmaceutical composition in accordance with claim
26 112 in which the amount of said C₄-C₈ sugar alcohol is from about 30 mg to about
27 1000 mg.
28

29 115.(new) A pharmaceutical composition in accordance with claim
30 112 in which the amount of said C₄-C₈ sugar alcohol is from about 100 mg to about
31 800 mg.

32 116.(new) A pharmaceutical composition in accordance with claim
33 105 in which said fed mode inducing agent is a member selected from the group
34 consisting of alkali and alkaline earth metal docusates.

35 117.(new) A pharmaceutical composition in accordance with claim
36 116 in which said fed mode inducing agent is a member selected from the group
37 consisting of calcium docusate and sodium docusate.

38 118.(new) A pharmaceutical composition in accordance with claim
39 116 in which said fed mode inducing agent is sodium docusate.

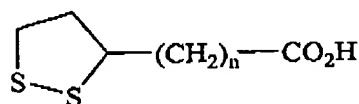
40 119.(new) A pharmaceutical composition in accordance with claim
41 116 in which the amount of said fed mode inducing agent is from about 30 mg to about
42 1000 mg.

43 120.(new) A pharmaceutical composition in accordance with claim
44 116 in which the amount of said fed mode inducing agent is from about 50 mg to about
45 400 mg.

46 121.(new) A pharmaceutical composition in accordance with claim
47 105 in which said fed mode inducing agent is a β -casomorphin.

48 122.(new) A pharmaceutical composition in accordance with claim
49 121 in which said β -casomorphin is bovine β -casomorphin.

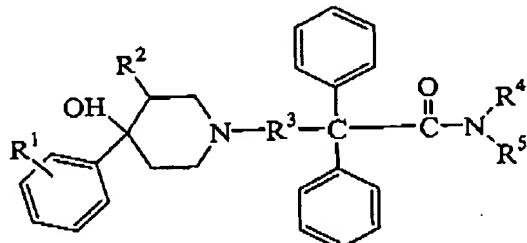
50 123.(new) A pharmaceutical composition in accordance with claim
51 105 in which said fed mode inducing agent is a dithioorganic acid of the formula



53 in which n is 3 to 13.

1 124.(new) A pharmaceutical composition in accordance with claim
2 123 in which said dithioorganic acid is α -lipoic acid.

3 125.(new) A pharmaceutical composition in accordance with claim
4 105 in which said fed mode inducing agent is a 2,2-diaryl-4-(4'-aryl-4'-
5 hydroxypiperidino)butyramide of the formula



6
7 in which:
8 R¹ is a member selected from the group consisting of H, lower alkyl, and
9 halo,
10 R² is a member selected from the group consisting of H and methyl,
11 R³ is a member selected from the group consisting of —CH₂CH₂— and
12 —CH(CH₃)CH₂—,
13 R⁴ is lower alkyl, and
14 R⁵ is lower alkyl.

15 126.(new) A pharmaceutical composition in accordance with claim
16 125 in which:
17 R¹ is a member selected from the group consisting of H, C₁-C₃ alkyl,
18 fluoro, and chloro,
19 R² is a member selected from the group consisting of H and methyl,
20 R³ is a member selected from the group consisting of —CH₂CH₂— and
21 —CH(CH₃)CH₂—,
22 R⁴ is C₁-C₃ alkyl, and
23 R⁵ is C₁-C₃ alkyl.

1 127.(new) A pharmaceutical composition in accordance with claim
2 124 in which R¹ is 4-chloro, R² is H, R³ is —CH₂CH₂—, R⁴ is CH₃, and R⁵ is CH₃.

3 128.(new) A pharmaceutical composition in accordance with claim
4 125 in which the amount of said 2,2-diaryl-4-(4'-aryl-4'-hydroxypiperidino)butyramide is
5 from about 0.5 mg to about 300 mg.

6 129.(new) A pharmaceutical composition in accordance with claim
7 125 in which the amount of said 2,2-diaryl-4-(4'-aryl-4'-hydroxypiperidino)butyramide is
8 from about 2 mg to about 15 mg.

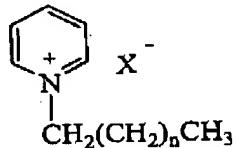
9 130.(new) A pharmaceutical composition in accordance with claim
10 105 in which said fed mode inducing agent is a member selected from the group
11 consisting of arginine and arginine salts.

12 131.(new) A pharmaceutical composition in accordance with claim
13 105 in which said fed mode inducing agent is a member selected from the group
14 consisting of the dipeptide Trp-Trp and Trp-Trp salts.

15 132.(new) A pharmaceutical composition in accordance with claim
16 131 in which the amount of said Trp-Trp is from about 0.05 mg to about 300 mg.

17 133.(new) A pharmaceutical composition in accordance with claim
18 131 in which the amount of said Trp-Trp is from about 0.5 mg to about 10 mg.

19 134.(new) A pharmaceutical composition in accordance with claim
20 105 in which said fed mode inducing agent is an alkyl pyridinium halide of the formula



21
22 in which n is 10 to 20 and X is halide.

1 135.(new) A pharmaceutical composition in accordance with claim
2 134 in which n is 12 to 16 and X is chloride.

3 136.(new) A pharmaceutical composition in accordance with claim
4 134 in which said alkyl pyridinium halide is cetyl pyridinium chloride.

5 137.(new) A pharmaceutical composition in accordance with claim
6 134 in which the amount of said alkyl pyridinium halide is from about 0.1 mg to about
7 200 mg.

8 138.(new) A pharmaceutical composition in accordance with claim
9 134 in which the amount of said alkyl pyridinium halide is from about 0.5 mg to about
10 50 mg.

11 139.(new) A pharmaceutical composition in accordance with claim
12 105 in which said fed mode inducing agent is a dihydroxybenzoic acid.

13 140.(new) A pharmaceutical composition in accordance with claim
14 139 in which said dihydroxybenzoic acid is gentisic acid.

15 141.(new) A pharmaceutical composition in accordance with claim
16 139 in which the amount of said dihydroxybenzoic acid is from about 3 mg to about
17 300 mg.

18 142.(new) A pharmaceutical composition in accordance with claim
19 139 in which the amount of said dihydroxybenzoic acid is from about 10 mg to about
20 100 mg.

21 143.(new) A pharmaceutical composition in accordance with claim
22 105 in which said fed mode inducing agent is retained in said dosage form in such a
23 manner that said fed mode inducing agent is released substantially immediately into
24 gastric fluid upon contact of said dosage form with said gastric fluid while said drug is
25 released into said gastric fluid in a sustained manner by dissolution and diffusion of said
26 drug out of said solid matrix, by erosion or dissolution of said matrix, or by osmotic
27 pressure within said solid matrix.

1 144.(new) A pharmaceutical composition in accordance with claim
2 105 in which said fed mode inducing agent is retained in said dosage form in such a
3 manner that both said drug and said fed mode inducing agent are released into gastric
4 fluid in a sustained manner by dissolution and diffusion of said drug and said fed mode
5 inducing agent out of said solid matrix, by erosion or dissolution of said matrix, or by
6 osmotic pressure within said solid matrix.

7 145.(new) A pharmaceutical composition in accordance with claim
8 105 in which said solid matrix is a member selected from the group consisting of
9 cellulose polymers and polyethylene oxide.

10 146.(new) A pharmaceutical composition in accordance with claim
11 145 in which said solid matrix is a member selected from the group consisting of
12 hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose,
13 hydroxypropylmethylcellulose, carboxymethylcellulose, and polyethylene oxide.

14 147.(new) A pharmaceutical composition in accordance with claim
15 145 in which said solid matrix is a member selected from the group consisting of
16 hydroxyethylcellulose, hydroxypropylcellulose, and polyethylene oxide.

17 148.(new) A pharmaceutical composition in accordance with claim
18 105 in which said fed mode inducing agent is contained in a solid coating adhering to a
19 surface of said solid matrix.

20 149.(new) A pharmaceutical composition in accordance with claim
21 148 in which said solid coating is comprised of said fed mode inducing agent suspended
22 in a water-soluble matrix.

23 150.(new) A pharmaceutical composition in accordance with claim
24 149 in which said water-soluble matrix is a member selected from the group consisting of
25 cellulosics, vinyls, glycols and carbohydrates.

26 151.(new) A pharmaceutical composition in accordance with claim
27 149 in which said water-soluble matrix is a member selected from the group consisting of
28 sodium carboxymethylcellulose, sodium starch glycolate, crospovidone, microcrystalline
29 cellulose, lactose, and substituted hydroxypropylcellulose.